

**Butler, Jennie C**

---

**From:** KUnger1217@cs.com  
**Sent:** Thursday, July 22, 1999 6:45 PM  
**To:** FDADockets@oc.fda.gov  
**Subject:** Docket # 98N-0044 Comment

July 22, 1999  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Dr.  
Room 1-23  
Rockville, Maryland 20857  
Re: Docket No. 98N-0044;

Gentlemen/Ladies:

This communication is in regards to the upcoming public meeting on Regulations on Statements made for dietary supplements concerning the effect of the product on the Structure or Function of the Body.

I must begin by stating up front that I am very concerned by the FDA's consideration of possibly undermining the will of the people as it was expressed through our elected representatives by the DSHEA act of 1994. I believe that this act represented a giant step forward in improving the health of the people of this great nation and I would be very distressed by what I believe may very well be a very giant step backward if the proposals as outlined by the FDA for discussion in your August meeting are adopted. I understand and appreciate your concern for the responsibility you feel in carrying out your duties of enforcing the laws regarding the interstate commerce of "misbranded and adulterated" drugs, food, and drinks. However, the crux of the problem continues to be "What is and who is going to determine what is "misbranded and adulterated"? Is it going to be just the FDA or is it going to be the people working in conjunction with the FDA as best they can through their elected representatives? The majority of Alternative Health Care Practitioners, including Chiropractors, Acupuncturists Herbalists, Massage Therapists, and many others have been virtually shouting from the rooftops for most of this century about the importance of diet and nutrition in Health Maintenance and Restoration. It is only recently that the NCI and Orthodox Medicine in general has begun to make this more of a corner stone of their philosophy. While I certainly applaud these moves, I think we owe it to ourselves to listen as carefully and completely as we can to what those outside of Traditional Medicine are saying about nutrition and related areas. We must admit that nutrition and the serious study about the possible healing and therapeutic qualities of anything existing in our natural environment is not something that is done to any great extent in most of our major Medical Universities. I hope that this will begin to change. I also think we are at a point where Traditional and Alternative approaches to health care are beginning to merge and there is the potential for them to generate a tremendously powerful synergistic whole which can only greatly enhance the overall health of the people in this country.

Our doctors and traditional medicine provide a necessary service and one which I believe, overall the majority provides very well. But I personally would very much like to see them reduce the use of prescription drugs whenever possible. The effect of drugs all too often is to simply erase or reduce the visibility of the symptom for which they were intended, do nothing to alleviate the original cause of the symptom, and lead to a variety of other problems which can be debilitating to a greater or lesser degree. Obviously there are exceptions, but in general, I think that drugs should pretty much be an emergency procedure. If one has severely elevated blood pressure or cholesterol or whatever, it may very well be appropriate to use a drug to reduce the levels. But THEN begin the search for the underlying cause and how to safely and effectively remove that cause using ALL reasonable methods and available resources.

To help them perform their functions more efficiently and successfully, I

98N-0044

C 22332

believe that each of us has an obligation, as well, to visit our doctors as informed as we can reasonably be and with a sense of responsibility for our own health. I believe that we are generally capable of intelligently discerning the information we receive in any form to help us do that. Thus I support and applaud the present approach that the FDA is taking in allowing certain implied claims and taking a more hands off approach until clear evidence warrants required action and I hope that this is the approach they continue to take.

Sincerely,

Ken Ungerecht  
7810 Clark RD. C78  
Jessup, MD. 20794